OPF 30.42

VIA ELECTRONIC FILING

<table>
<tr><td rowspan="8">DECLARATION OF NIGEL BATES UNDER 37 CFR 1.132

Address to:
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450</td><td>Attorney Docket No.</td><td>KEMP-002</td></tr>
<tr><td>Confirmation No.</td><td>8277</td></tr>
<tr><td>First Named Inventor</td><td>KENDALL, MARK ANTHONY FERNANCE</td></tr>
<tr><td>Application Number</td><td>10/031,627</td></tr>
<tr><td>Filing Date</td><td>September 26, 2002</td></tr>
<tr><td>Group Art Unit</td><td>3767</td></tr>
<tr><td>Examiner Name</td><td>Huh, Benjamin</td></tr>
<tr><td colspan="2">Title: “NEEDLELESS SYRINGE”</td></tr>
</table>

Sir:

1. I, Nigel Bates, have been employed for over six years by POWDERMED LIMITED (or it's predecessor companies) who in turn control POWDERJECT RESEARCH LIMITED, the Assignee of the above-identified patent application, and have a very good theoretical and practical knowledge of the needleless syringe products that are being developed.

2. I have reviewed the above-identified patent application (USSN 10/031,627) and the Bellhouse document (US 5,630,796).

3. I have read the Office Action dated November 1, 2007 in this application and understand that the Examiner has rejected pending claims 1-7, 9-25, 27-34, 36, 37 and 55 on the basis that they are allegedly anticipated by and/or obvious over the Bellhouse document (US 5,630,796), either alone or in combination with additional references. Additionally, I understand that the Examiner has rejected claim 20 for failing to comply with the enablement requirement.

THE BELLHOUSE DEVICE

4. The “nozzle” is labeled 26 (see line 22 of column 12). As discussed at lines 44 to 46 of column 12, the nozzle has an upper convergent part 35 and a lower divergent part 37. In between these two parts is a throat 36. The purpose of the convergent-divergent nozzle is to accelerate the gas and particle mixture to supersonic

speeds. The use of convergent-divergent nozzles to achieve supersonic fluid flows is well known in the fluid dynamic arts.

5. The part labeled 38 in Figure 1 of Bellhouse is not a nozzle. Instead, this is a divergent spacer shroud 38 that is designed merely to offset the end of the nozzle 26 from the target surface (see lines 48 to 51 of column 12 of US 5,630,796). Upon exiting the nozzle 26, the gas and particles form a free jet until they reach the target surface. The sides of the divergent spacer shroud 38 are sufficiently far away from this free jet to not influence it. The sides could be made with virtually any suitable shape and the divergence or otherwise of this spacer shroud is not essential in order to carry out its function. The function of the shroud is merely to channel any gas rebounded from the target surface through the baffle 41 that performs the silencing operation. This is explained at lines 21 to 34 of column 13 of Bellhouse.

6. The particles are located in the capsule 28 shown in Figure 1 and shown in more detail in Figure 8. It can be seen that the passage immediately upstream of the membrane 34 converges in the flow direction. The passage immediately downstream of the membrane 34 continues to converge in convergent part 35. Thereafter a throat 36 is formed and the passage thereafter diverges in divergent section 37. The following divergent spacer shroud 38 is irrelevant in terms of the gas dynamics.

7. The variation of the cross-section in the divergent section 37 of the nozzle 26 disclosed in Bellhouse is extremely significant in terms of the gas dynamics. As specified in the paragraph bridging columns 14 and 15 of Bellhouse, the divergent section diverges from a diameter of 1.5mm at the throat to a diameter of 2.23mm at the nozzle exit. This corresponds to a flow area ratio of 2.21. This is very significant in terms of the gas dynamics because, as is well known in the art of convergent-divergent nozzles, the degree of acceleration of the gas flow is determined by the area ratio of the nozzle.

8. The relationship between nozzle cross-sectional area and gas velocity is often described by the following equation

$$\frac{A}{A^*} = \frac{1}{M}\left[\frac{1+\frac{k-1}{2}M^2}{1+\frac{k-1}{2}}\right]^{\frac{k+1}{2(k-1)}}$$

where:

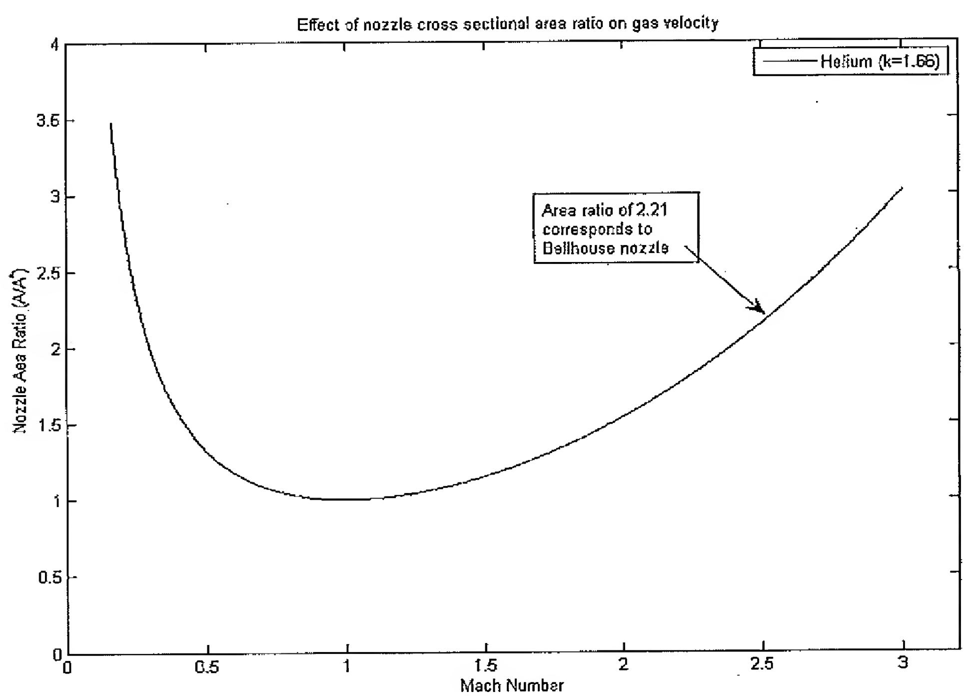
A = nozzle cross-sectional area

A* = nozzle cross-sectional area at critical condition where Mach Number is unity (i.e. at the throat)

k = ratio of specific heats (= 1.66 for helium)

M = exit Mach Number (ratio of flow velocity to local sonic velocity)

A plot of the nozzle cross sectional area ratio, A/A*, versus Mach number, using this equation, clearly shows that a converging-diverging passage with a section of minimum area is required to accelerate the flow from subsonic to supersonic speed. The critical point where the flow is just at sonic velocity (M=1 at A/A*=1) is seen to exist at the throat of the nozzle. The exit velocity calculated for the Bellhouse nozzle is Mach 2.54.



9. The convergent-divergent nozzle of Bellhouse is thus very significant, because it will accelerate a flow to Mach 2.54, provided enough gas energy is supplied. If not enough gas energy is supplied, a shock wave will form in the nozzle.

10. Figures 1 and 2 and the discussion from line 32 of page 1 to line 33 of page 3 of USSN 10/031,627 show the results of experiments to measure the gas flow properties of the device described in Bellhouse.

11. These experimental results prove to me that the particles that are emitted from the Bellhouse device are accelerated by two separate mechanisms, neither of which can be characterized as a "quasi-steady flow" mechanism.

12. Figure 1 of USSN 10/031,627 shows that a series of shockwaves 11, 13, 16, 14 flow downstream from the membrane bursting position and decelerate as they move. As such, the particles 17 catch them up and cross through the shockwaves. This is illustrated in Figure 1 by the particle trajectory 17 that crosses the lines labeled 16. At the same time, a shockwave 15 created at the exit plane moves in the upstream direction towards the membrane burst point. This occurs as the driver pressure from the reservoir decreases. The particles 17 accordingly also pass through this shockfront 15 as it moves upstream. As described at line 20 of page 5 of USSN 10/031,627 and as shown in Figure 1, quasi-steady supersonic flow occurs solely in region 3 of the Bellhouse device and occurs only at a very small portion of the device near to the membranes. At no point in the working of the Bellhouse device does the quasi-steady flow region 3 extend all the way to the nozzle exit. The reason for this is that Bellhouse does not disclose a properly expanded nozzle. The gas pressures and nozzle geometries disclosed in Bellhouse inevitably lead to shock waves forming in the nozzle in use.

13. The experiments described in USSN 10/031,627 thus conclusively prove to me that the particles of Bellhouse are not accelerated by substantially quasi-steady flow for the duration of time that the particles are in the duct section. As can be seen from Figure 1, any quasi-steady flow occurs only in the upstream part of the device (close to where the membrane is) and moves downstream at a very slow speed such that it never actually interacts with any particles. Accordingly, very few particles, if any at all, are accelerated by the quasi-steady flow in the Bellhouse device. Any particles that are entrained by quasi-steady flow are so entrained for only a very brief moment before passing through shock from 14 into a region of non-quasi-steady flow attributable to the starting process (region 1 in Figure 1). Accordingly, no particle is accelerated by quasi-steady flow for the duration of time that the particles are in the duct section.

THE CLAIMED INVENTION

14. USSN 10/031,627 discloses several designs which would enable one of ordinary skill in the art to make and use a needleless syringe falling within the scope of claim 20. Figures 3 to 7 disclose exemplary embodiments. These are described at pages 11 to 18 of the description of USSN 10/031,627. In my opinion, sufficient details are given to enable one of ordinary skill in the art to fully work the invention within its claimed scope. In particular, there appear to be no important parameters or dimensions that are left unmentioned in the specification but whose value is important in ensuring that the claimed invention is obtained.

15. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date: 26 Nov 05 By: N Bates

Nigel Bates

CURRICULUM VITAE

NAME: Nigel Bates

JOB TITLE: Technical manager

DEPARTMENT: Device Development

START DATE: 1 May 2001

1. EDUCATION

MSc Manufacturing Systems Engineering – Warwick University	1993
MSc Polymer Science and Technology - North London Polytechnic	1985
Graduate Membership Royal Society of Chemistry – Bristol	1977
HNC Chemistry & ONC Sciences	1974

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2. MEMBER OF PROFESSIONAL SOCIETIES

Member Royal Society of Chemistry

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3. PATENTS/PUBLICATION

B. E. Eastwood, P. A. Christensen, R. D. Armstrong, and N. R. Bates, 'The Electrochemical Oxidation of a Carbon Black -Loaded Polymer Electrode in Aqueous Electrolytes', *Journal of Solid State Chemistry*, 1999, **3**, 179 - 186.

US5262718 & EP0223615 Anisotropically electrically conductive article
US4865892 & EP0257886 Dimensionally recoverable article
US4764422 & EP0213774 Electrically conductive composite article
CA1284523 Uniaxially electrically conductive articles with porous insulating substrate
DE3682150D, DE3678104D, AT68908T, AT61690T & CA1267942

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4. HONOURS/AWARDS

Chartered Chemist
Chartered Scientist
Accredited Lloyds ISO 9000 Auditor

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5. PREVIOUS JOBS/POSITIONS
(brief description of responsibilities and date position held)

Technical Manager – PowderMed/PowderJect Oct 2002 – To date
Manage device development and engineering for PMED delivery system development and manufacture on Therapeutic and Prophylactic vaccine projects. Project leader for the Multi-Use PMED device development project. Supervise Device technologist, device technician and toolmaker.

Technical Evaluation Section Manager – PowderJect Sept 2001 – Oct 2002
Providing technical support for project activities within Device Engineering and Delivery Systems. Supervision of laboratory technicians and engineering workshop toolmaker.

Senior Project Engineer – PowderJect May 2001 – Sept 2001
Providing engineering support for CVF project.

Project Manager – BD Pharmaceutical Systems April 2000 – May 2001
Management of major capital projects for medical device development and manufacture, management of multi-skilled project teams, consultation on materials selection and materials issues

Technical Manager – Raychem Electronics OEM 1997 – Sept. 1999
Management of Quality Engineering Function and projects, managed a team of engineers and project teams, implementation of Quality Systems in manufacturing and development environment. Member of the quality management team.

Technology Manager – Raychem Corporate Technology 1992 – 1997
Management of a portfolio of materials science research and development projects for the electronics and aerospace markets. Responsible for a team of scientists and engineers. Member of the senior management team.

Early Career

Product Manager – Raychem Ltd	1991 – 1992
Process Engineering Manager - Raychem Ltd	1988 – 1991
Project Manager - Raychem Ltd	1986 – 1988
Senior Technologist - Raychem Ltd	1981 – 1986
Product Development Technologist – Robnorganic systems	1980 – 1981
Assistant Works Controller/Chemist	1975 – 1980
Senior Product Development Technician	1970 – 1975
Assistant Scientific Officer	1970 - 1970